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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,383	12/22/2000	Peter Van Vlasselaer	4750-0001.30	9470

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 01/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/747,383

Applicant(s)

VLASSELAER ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Applicant's election of without traverse of species "infectious lung disease" in Paper No. 5 is acknowledged. Applicant has further elected Group II (claims 15-21) in Paper No. 7 without traverse and cancelled claims 1-14. However, since the Applicant has elected to cancel claims 1-14 the species election is moot. Thus claims 15-21 are pending.

### *Drawings*

2. The drawings have been objected to by the draftsman (see attached 948).  
Appropriate correction is required.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### 1. **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsman.

#### 2. **Corrections other than Informalities Noted by Draftsman on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsman, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

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### **Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

### ***Specification***

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Objections***

4. Applicant's numbering of the sub parts of claim 15 is confusing. Renumbering of claim 15 is requested.

5. In claim 15, part (b) (vi) should be rewritten as two or more of the above size ranges

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6a. Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huland et al. (U. S. Patent No. 5,780,012) in view of both Debs et al. (J.of Imm. Vol. 140: 3482-3488) and Ruskewicz et al. (U. S. Patent No. 5,971,951).

Huland et al. teaches various aerosol compositions containing cytokines for reducing lung afflictions. The reference teaches various examples in which cytokines have been combined with mannitol and polysorbate like polysorbate 80 (see example 5). Although the specific example teaches that the composition contains 5 mg of mannitol, the specification also recites that the mannitol concentration could be 0.001 mg/ml to about 0.020 g/ml that includes the limitation of claim 18 (column 5, lines 55-60). In addition, the reference also teaches that the composition contains detergents as dispersing agents. These agents including polysorbate are present in a concentration of about 0.01mg/ml to about 0.5 mg/ml that includes the limitation of claim 20 (column 5, line 60- column 6, line 5). The composition contains about one million units of cytokines (column 6, lines 41-43). The composition containing mannitol and polysorbate in the above mentioned concentrations would have comparable viscosity to that of claim 21 and be capable of being aerosolized. This is because the viscosity of a compound at a given temperature is proportional to the radius of the capillary. Although Huland et al. describe cytokine IL-2 extensively, they also describe interferon gamma (column 4, lines 53-54). However, the reference does not expressly discuss the volume diameter of the droplets used in the delivery.

The Debs et al. reference teaches the use of aerosolized IFN-gamma to stimulate alveolar macrophage and blood monocyte function (abstract). It also discusses that IFN-gamma activates macrophages to release IL-1, express class II HLA (Ia) surface Ag, and lyse tumor cells. Although the reference does not expressly discuss the stimulation of HLA-DR antigen expression, stimulation of HLA-DR antigen expression is an inherent property of IFN-gamma as indicated by Weller et al. (1993).

Ruskewicz et al. is relied upon to describe the aerosol extrusion mechanism. It teaches that when the formulation is forced through the flexible porous membrane it will form an aerosol preferably having a particle size in the range of about 1 to 12 microns, more preferably of about 3.0 to 6.0 microns (column 17, lines 57-60).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a composition containing mannitol and polysorbate with a specific viscosity, as described by Huland et al., because Debs et al. teaches that the aerosolized IFN-gamma can be delivered to respiratory tract and is capable of stimulating HLA-DR antigen expression; Ruskewicz et al. teaches the aerosol extrusion mechanism. One of ordinary skill in the art would have been motivated to use aerosolized IFN-gamma generated by forcing the composition thru defined-size openings to deliver to the respiratory tract specifically to stimulate HLA-DR antigen expression. Thus the claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary. Therefore, the instant invention is obvious over Huland et al. (U. S. Patent No.

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5,780,012) in view of Debs et al. (J.of Imm. Vol. 140: 3482-3488) and Ruskewicz et al. (U. S. Patent No. 5,971,951).

7. No claims are allowable over the prior art.

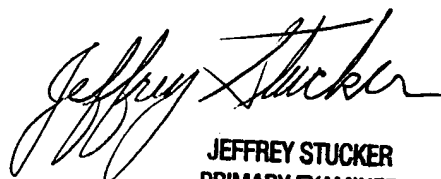
#### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS  
January 10, 2003

  
**JEFFREY STUCKER**  
**PRIMARY EXAMINER**